DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-962/S-007

Abbott Laboratories
Attention: Christine L. Hanke
Senior Specialist, Regulatory Affairs
D-389, Bldg AP 30
200 Abbott Park Road
Abbott Park, Illinois 60064-3537

Dear Ms. Hanke:

Please refer to your supplemental new drug application dated July 17, 1998, received July 21, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Manganese Chloride Injection, USP.

We acknowledge receipt of your submission dated August 29, 2003. The submission of August 29, 2003, constituted a complete response to our December 27, 2001, action letter.

This supplemental new drug application provides for "Geriatric Use" information in the Package Insert. The wording on "Geriatric Use" in this application (S-007) is identical to the wording approved in the action letter dated December 27, 2001, and is as follows:

> "*An evaluation of current literature revealed no clinical experience identifying differences in response between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other therapy.*"

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on August 29, 2003.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane

Rockville, MD 20857

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Holly Wieland, Regulatory Project Manager, at (301) 827-6410.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Office of Drug Evaluation II
Division of Metabolic and Endocrine Drug Products HFD-510
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

David Orloff

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